

SEXUAL HEALTH COLLECTION KIT

A vaginal swab sample collection kit used for the collection and transportation of samples for laboratory analysis of sexually transmitted infections by nucleic acid technique (NAT)

This kit contains the materials required for either sample self-collection or collection by a health/social care professional.

IVD For *in vitro* diagnostic use, sample self-collection

REF KT357W

CUK RA

i Carefully read the enclosed instruction leaflet before use

! Important: Do not use kit if security seal is broken. Keep out of reach of children

⌘ Do not re-use

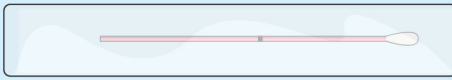
18+ For use by persons aged 18 and over

Sample collection instructions (Steps 1-14)

- Please ensure the kit is within expiry date and read these instructions carefully and completely before attempting to collect the sample.
- If your kit requires online activation, please follow the instructions provided by your healthcare organisation. If you need assistance please contact the healthcare organisation who arranged the test.

Your sample collection kit contents

Please check that the kit contains all of the items outlined below. Do not proceed with sample taking if any items are missing or damaged, contact the healthcare organisation who arranged your test for assistance.



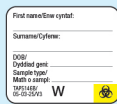
Sample collection swab, CC **STERILE EO**



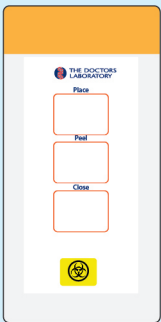
Return security label



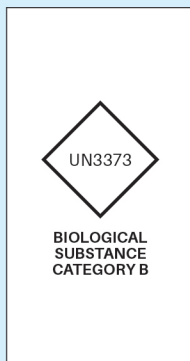
Swab specimen transport tube, **IVD**



Sample label



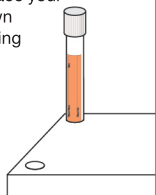
Transport pouch with absorbent pad



Return postal box

IMPORTANT!

The kit contents are supplied in a tray, please empty the tray contents and push through the holes in the base. Then turn the tray upside down and place your tube as shown when collecting your sample.



VAGINAL SWAB SAMPLE COLLECTION

1 If not already pre-populated please complete the test request form, provided by your doctor/clinic, separate to this kit. **Make sure the sample date is completed.**



2 Clearly complete the sample collection tube label using a ball point pen with:

- Your First name
- Your Surname
- Your Date of birth
- Sample type: Vaginal

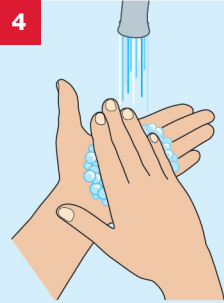


3 IMPORTANT SAMPLE TRACKING INFORMATION!

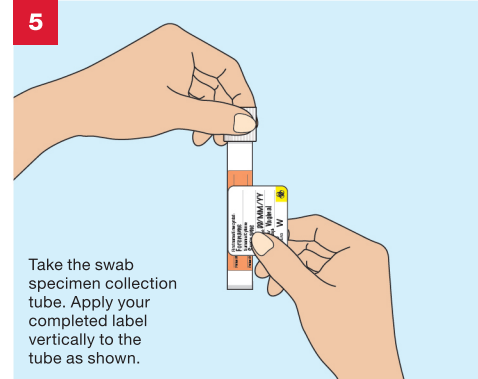
The return postal box has a postal tracking label applied. Please make a note of the unique tracking number displayed under the barcode on the postal tracking label, as shown below. Keep this in a safe place for future reference. **You can track delivery of your Royal Mail parcel by entering this number using the following link:** <http://www.royalmail.com/track-your-item>



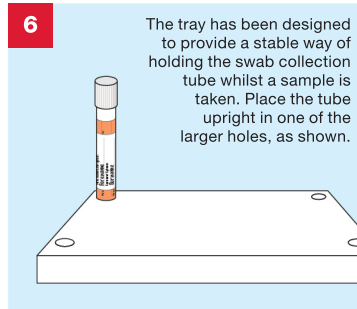
Write your tracking number here for reference – keep this safe.



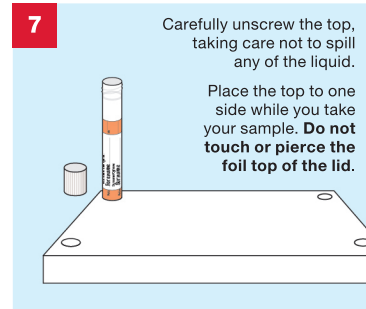
Wash hands using soap and water and dry them.



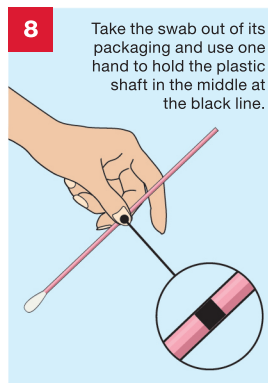
Take the swab specimen collection tube. Apply your completed label vertically to the tube as shown.



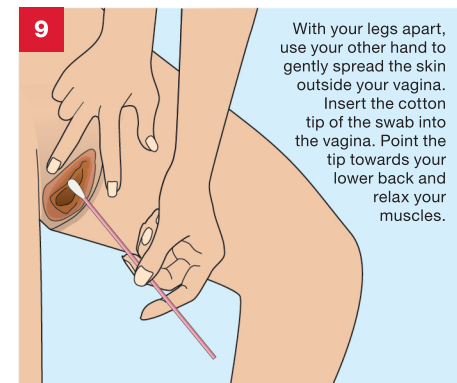
The tray has been designed to provide a stable way of holding the swab collection tube whilst a sample is taken. Place the tube upright in one of the larger holes, as shown.



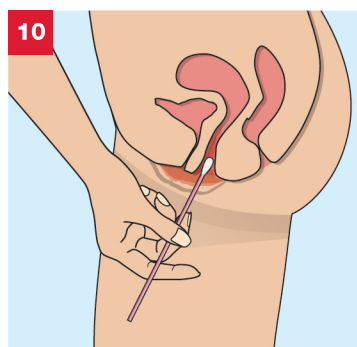
Carefully unscrew the top, taking care not to spill any of the liquid. Place the top to one side while you take your sample. **Do not touch or pierce the foil top of the lid.**



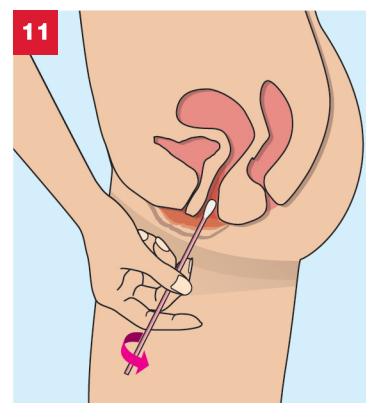
8 Take the swab out of its packaging and use one hand to hold the plastic shaft in the middle at the black line.



9 With your legs apart, use your other hand to gently spread the skin outside your vagina. Insert the cotton tip of the swab into the vagina. Point the tip towards your lower back and relax your muscles.



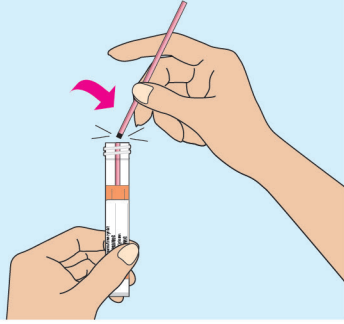
10 Gently insert the swab about 5cm into your vagina. Your fingers on the black line will stop you going in too far. If the swab does not slide easily, gently rotate it as you put it in. If it is too difficult, do not attempt to continue.



11 Rotate the swab for 5 seconds (count to 5 slowly), making sure it touches the walls of your vagina. Carefully pull out the swab.

12

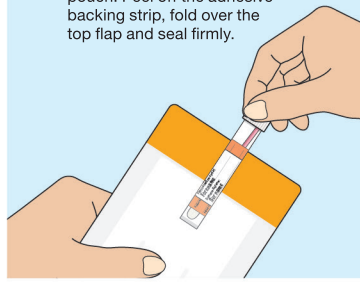
Carefully put the swab into the collection tube. Holding the tube steady, snap the stick off at the black line.



13

Discard the stick end of the swab in a bin, leaving the cotton end in the liquid. Screw the cap back onto the tube tightly.

Place the tube into the transport pouch. Peel off the adhesive backing strip, fold over the top flap and seal firmly.



14 IMPORTANT CHECKLIST

Before you return your sample please do the following:

- Place your completed request form supplied by your doctor/clinic into the kit tray
- Make sure the swab specimen transport tube is labelled
- Make sure that the swab specimen transport tube is in the transport pouch and this is firmly sealed
- Place the transport pouch into the kit tray
- Slide the kit tray back into the return postal box
- Close the return postal box and apply the return security label to seal the end of the box
- Check that you have taken note of your postal tracking number

Please store at room temperature until posted.

Please post your sample to **The Doctors Laboratory** as soon as possible (ideally on same day or within 24 hours of sample collection) from **ANY** Royal Mail post box in the UK. No stamp is required within the UK.

If you need assistance please contact The Doctors Laboratory on 020 7307 7373 or email samples@tdlpathology.com.

KEY TO SYMBOLS

| | | | | |
|----------------------------------|--|---|------------------------------|-------------------------------------|
| IVD | For in vitro diagnostic use | Manufacturer | UK CA | UK Conformity Assessed |
| REF | Catalogue number | EC REP | | EU Authorised Representative |
| LOT | Batch code | Use by end of year-month | CE | EU Conformity Assessed |
| STERILE EO | Sterilized using ethylene oxide | Temperature limits: 4°–25°C | Do not re-use | |
| Biological risk. | Biological sample, treat as potentially infectious | Caution, consult accompanying documents | Consult instructions for use | |
| Do not use if package is damaged | | Keep away from sunlight | 18+ | For use by persons aged 18 and over |
| Distributor | | Keep dry | | |

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Website: www.real-digital.co.uk

The Doctors Laboratory Limited
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RDI-IFU-022, TAP5139B/28-04-25/V9. Issue No. 3; Date 28/04/25.

| Revision/Date | Change summary |
|---------------|--|
| 1 03/2023 | Initial RDi product for UK market |
| 2 09/2023 | Minor translation changes |
| 3 04/2025 | Componentry change: secondary and outer packaging. |

Any serious incidents that occur in relation to the use of this device, should be reported to Real Digital International.

Warnings and precautions

- This kit is designed for use by persons aged 18 and over and upon request of a healthcare professional or healthcare organisation.
- Please consult with a healthcare professional for guidance on sample collection processes for adolescent and younger children.
- The kit should not be used by individuals lacking the physical or mental capacity to correctly follow the self-collection instructions. If you have problems or feel unwell or lightheaded during the collection process, please pause and if necessary, consult with your advising healthcare professional.
- If you have experienced recent pelvic pain, pain during or as a result of sexual intercourse and/or unusual vaginal discharge or odor please discuss this with your healthcare professional before collecting your sample.
- The Hologic transport buffer contains no substances which at their given concentration, are considered to be hazardous to health. In the case of contact with eyes, skin or mouth please and rinse thoroughly with clean water, if ingested please drink plenty of water and if any symptoms occur please consult a medical professional. In the case of spillages please wipe with absorbent paper and dispose in normal household waste. For further information please refer to safety datasheets which can be found at www.hologic.com or contact MolecularSupport@hologic.com.
- Samples arriving at the laboratory which show evidence of the below may not be tested:
 - Leaking sample/no liquid present in collection tube
 - No swab inside the collection tube
 - Two or more swabs inside the collection tube
 - Swab placed upside down in the collection tube
 - More than 1 collection tube per return box
 - Different swab type/brand to the one supplied
 - General damage
- The sample collection swab has a score line, which after sampling helps the swab break at the correct position when pressure is applied to allow it to fit in the collection tube. If this score line is broken, appears damaged or the swab arrives in two broken parts, do not use and request another kit from your healthcare organisation.
- Use with caution if allergic to nylon fibre and ABS (Acrylonitrile butadiene styrene) material. If any problems arise during the sample collection process please contact your healthcare organisation.
- The accuracy of your results may be compromised if you do not read and follow the instructions in full.
- Samples arriving at the laboratory which show signs of degradation or general damage or arrive after 60 days (Aptima swab) of sample taking may not be tested.

Materials required but not provided

- **Test request form.** This will be provided by your healthcare professional or healthcare organisation. **Please complete the request form with your details as instructed.**

Laboratory Tests

- The tests and procedures undertaken by The Doctors Laboratory Limited are verified and performed in line with supplier product instructions for use and supported by additional validation data for use with self-collection procedures.
- Test results are provided in line with clinically approved results pathways, agreed between The Doctors Laboratory Limited and the patients designated healthcare professional or healthcare organisation.